

REMARKS

Claims 1-11 are pending. Claim 1 has been amended in order to clarify the scope of the invention. Support for the amendment to claim 1 can be found throughout the specification, but specifically at page 10, lines 5-12. No new matter has been introduced as a result of the amendment.

2. Response to rejection of claims under 35 U.S.C. § 103

Claims 1-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Edelmann et al. in view of Wong.

Applicant respectfully responds as follows:

Applicant incorporates the legal arguments set forth in the Response to First Office Action by reference herein. Examiner has not established a *prima facie* case of obviousness. Examiner has failed to demonstrate any of the criteria required for a showing of *prima facie* obviousness, particularly, the requirements that there be a suggestion or motivation to modify the cited references or combine the reference teachings, and that all of the claim limitations be taught or suggested by the prior art. In addition, when a prior art reference is considered by the Examiner, it must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983); M.P.E.P. § 2141.02. In other words, a reference that teaches away from the claimed invention does not constitute a proper prior art reference against the claimed invention.

The presently claimed invention, as amended, is drawn to a method of regenerating a biosensor wherein a biosensor that measures the levels of one or more components in a sample, is regenerated by washing, and wherein the washing, *i.e.*, **rate of increase of the**

flow rate of the background fluid, occurs essentially simultaneously with the entry of the sample aliquot into the sensor. In other words, as set forth in claim 1, the measurement of the sample is seamlessly integrated with the washing/regeneration process and occurs simultaneously. None of the references cited by the Examiner teach the claimed invention.

The combination of Edelmann et al. and Wong does not result in the claimed invention. As the Examiner has already conceded, “Edelmann does not specifically disclose regenerating the biosensor by increasing the flow rate of the buffer after detecting the analyte.” *See* Final Office Action at p.3. However, according to the Examiner, Wong cures the defect in Edelmann because “turbulent flow [disclosed in Wong] has the same effect as increased rate of a laminar flow; therefore it would have been obvious for anyone of ordinary skill in the art to modify Edelmann’s method by simply increasing the flow rate of the washing buffer....” The Examiner has liberally interpreted the disclosure of Wong to include elements not in evidence or otherwise disclosed. To state that the turbulent flow of buffer disclosed in Wong is the same as the measured increased flow rate of buffer claimed in the present invention is neither correct nor grounded in objective evidence. Furthermore, a close reading of Wong indicates that maintaining the flow rate of the infusion/calibration fluid at the same predetermined flow rate before and during the measurement step is a critical feature of the Wong invention. *See* col. 3, lines 47-51 (The control system for the assembly advantageously controls the flow of fluids such that the infusion fluid is used for calibration and is made to flow through the electrode assembly during calibration at a predetermined flow rate.); *see also*, col. 4, lines 26-29 (That is, substantially the same flow rates are used in the infusion line through the electrode assembly when infusion fluid flows during calibration and also when blood flows during

measurement.) The maintenance of the same flow rate during calibration and measurement is an advantage of the Wong invention because it “eliminates any effect the fluid rate might otherwise have on the measurements.” *See* col. 3, lines 54-56. In other words, one of ordinary skill in the art would not have been motivated to increase the flow rate after reviewing the Wong reference, because the Wong reference **teaches away** from increasing the flow rate of the calibration buffer.

Furthermore, the Examiner has combined the Edelman and Wong references without making a showing of the requisite motivation to do. Under the teachings of *In re Fine*, *In re Zurko* and *In re Lee*, mere conclusory assertions stating that the references relied upon teach all aspects of the claimed invention is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. The Examiner has not addressed this improper combination issue in the office action mailed on May 26, 2004, thereby forcing Applicant to raise it again. In addition, as discussed above, modifying the Wong invention by increasing the calibration buffer flow rate in the would render the Wong invention unsuitable for its intended purpose. Therefore, there is no suggestion or motivation to make the proposed modification, *i.e.*, increasing the flow rate of the calibration buffer, to the Wong reference. M.P.E.P. § 2143.01.

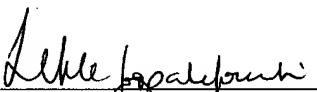
CONCLUSION

In conjunction with the claim amendments and arguments set forth above, Applicant believes that it has addressed all of the Examiner's concerns and rejections. Applicant believes that the claims are now in condition for allowance and respectfully requests that the Examiner grant such an action. If any questions or issues remain in the

resolution of which the Examiner feels will be advanced by a conference with the Applicant's attorney, the Examiner is invited to contact the attorney at the number noted below.

No fees are believed to be due in connection with this submissions. However, if any fees are due, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account 10-0447 (Reference No. 45687-00008).

Respectfully submitted,



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